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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,403	06/04/2001	Pramod K. Srivastava	8449-178-999	1802

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/873,403	Applicant(s) SRIVASTAVA ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,40 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-9,40 and 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Srivastava et al

1. The amendment filed 3/23/2005 is acknowledged and entered into the record. Accordingly, claims 2-6,10-39, and 41 are canceled without prejudice or disclaimer.
2. Claims 1,7-9,40, and 42-50 are pending and examined on the merits
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 1,7-9,40, and 42-50 under 35 USC § 112, 1st paragraph as lacking adequate written description is maintained for the reasons of record. Applicant argues that the application as filed supports the written description for the genus of antigenic molecules claimed. To support this assertion, applicant provides the legal standards for written description by citing the cases of *Vas-Cath Inc. v. Mahurkar* and *Regents of university of Cal. V. Eli Lilly & Co.* and also points to the Written Description guidelines. Applicant specifically points out that provided in the guidelines are circumstances wherein one species would be representative of an entire genus and further go on to argue that a “representative number” depends on the ability of the skill artisan to recognize the members of the genus given the disclosure of a species. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

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When there is substantial variation in the genus, one must describe a sufficient variety of species to reflect the variation within the species. In the instant case, the genus of antigenic molecules is a large and highly diverse genus of molecules that differ one from the other in sequences and structure. Moreover, the findings of *Eli Lilly* indicated that written description can be met by reciting structural features common to the genus, wherein the features constitutes a substantial portion of the genus. The applicant's specification has not provided one of skill in the art with representative numbers of species that reflect the variation within the genus, by disclosure of common attributes, structures or a disclosed correlation between structure and function. One of skill in the art would therefore find it difficult to recognize that the applicant was in possession of the highly large and diverse genus of antigenic molecules claimed.

Applicant further argues that the case law relied upon in making the written description rejection (i.e. *The regents of the University of California v. Eli Lilly*, 119 F3d 1559, 1568 (Fed Cir. 1997), cert. Denied, 523 US.1089 (1998)) is not applicable to the instant case because the *Eli Lilly* case was drawn to cDNAs while the instant invention does not concern nucleic acids. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be

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achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed. Cir. Feb. 13, 2004).

Applicant additionally contends that the instant case is analogous to example 16 of the Written Description guidelines (see page 59) wherein the example analyzes the written description of an antibody concluding that in well-developed or routine arts, such as in the production or manufacturing of an antibody, the specification need not disclose or provide written description for the genus because such disclosure is implicitly disclosed in the specification. Applicant contends that antigenic molecules fall into this class of well-developed arts and therefore need not be fully disclosed. Applicant supports this argument by pointing to general teachings in the specification, regarding potential antigens, and to the art wherein the art allegedly provides means of identifying and producing antigenic molecules. Applicant concludes by indicating that given the maturity of the art with regard determining, producing, and identifying antigenic molecules, one of skill in the art would conclude that the applicant was in possession of the full spectrum of antigenic molecules claimed. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The specification of the instant application has not provided a clear depiction of the claimed invention in the way of a complete detailed description, partial structure, or

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correlation between structure and function of the claimed antigenic molecule. What applicant relies on is the general knowledge and skill of the artisan to supplant the specific disclosure needed in a highly vast and diverse genus of antigenic molecules. The reliance on general knowledge and level of skill in the art does not supplement the omitted description of the genus of antigenic molecules claimed, because specific, not general guidance is required.

Therefore, since the instant disclosure fails to provide one of skill in the art with adequate written description, the rejections are maintained for the reasons of record.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/23/2005.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
June 8, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/10/05